

II. REMARKS

Claims 1-20 are pending and are restricted as between the 11 Groups set forth below. Claims 2-17 and 20 have been amended as shown above. In particular, dependent claim 17 has been amended from dependent to independent form, thereby making explicit what was previously implicit. Claim 20 has been canceled, without prejudice or disclaimer. In addition, claims 2-13 have been amended to depend from claim 17 rather than claim 1, thereby specifying that the modified zinc finger protein is encoded by an isolated polynucleotide, as described throughout the specification, for example in the paragraph beginning on line 18 of page 6. Similarly, claim 14 (and claims 15 and 16, depending therefrom) have been amended to specify that the fusion protein is encoded by an isolated polynucleotide. Applicants further note that the above amendments are fully consistent with Applicants' provisional election of Group X (and further provisional election of Group I). No new matter has been added as a result of these amendments and entry thereof is respectfully requested.

Restriction Requirement

Claims 1-20 are subject to restriction as between the following Groups:

Group I (claims 1-4), drawn to a modified plant zinc finger protein that binds to a target DNA sequence of 3 or more contiguous nucleotides, class 530, subclass 300;

Group II (claims 1, 5 and 6), drawn to a modified plant zinc finger protein comprising a tandem array of zinc fingers, wherein one or more of the zinc fingers are obtained by rational design, class 530, subclass 377;

Group III (claims 1, 5, 7 and 8), drawn to a modified plant zinc finger protein comprising a tandem array of zinc fingers, wherein one or more of the zinc fingers are obtained by selection, class 530, subclass 350;

Group IV (claims 1, 5 and 9), drawn to a modified plant zinc finger protein comprising a tandem array of zinc fingers, wherein one or more of the zinc fingers comprise canonical C₂H₂ zinc fingers, class 530, subclass 324;

Group V (claims 1, 5 and 10), drawn to a modified plant zinc finger protein comprising a tandem array of zinc fingers, wherein one or more of the zinc fingers comprise non-canonical zinc fingers, class 530, subclass 370;

Group VI (claims 1, 5 and 11), drawn to a modified plant zinc finger protein comprising a tandem array of zinc fingers, wherein one or more of the zinc fingers are derived from two or more plant species, class 530, subclass 370;

Group VII (claims 1, 5, 12 and 13), drawn to a modified plant zinc finger protein comprising a tandem array of zinc fingers, wherein one or more amino acid residues are deleted or substituted as compared to a naturally occurring plant zinc finger protein, class 435, subclass 440;

Group VIII (claims 14-15), drawn to a fusion polypeptide comprising a modified zinc finger domain and at least one functional domain that is a repressive domain, class 435, subclass 69.7;

Group IX (claims 14-16), drawn to a fusion polypeptide comprising a modified zinc finger domain and at least one functional domain that is an activation domain, class 530, subclass 370;

Group X (claims 17-19), drawn to an isolated polynucleotide, class 536, subclass 23.6;
and

Group XI (claim 20), drawn to a method for modulating gene expression in a plant cell, class 514, subclass 2.

In addition, if Group X is elected, Applicants are required to select a single type of polynucleotide encoding a single type of zinc finger protein set forth in Groups I-VII.

Applicants provisionally elect Group X and the type of zinc finger protein set forth in Group I, **with traverse**. Although the arguments set forth below in support of traversal are directed to claims reciting polypeptides as filed, Applicants note that these arguments are equally applicable to the elected polynucleotide claims.

In support of this restriction requirement, the Examiner asserts that the claims of each group are patentably distinct. However, Applicants note that two criteria must be met for a proper restriction requirement under M.P.E.P. § 803: (1) the inventions must be independent or distinct as claimed; and, in addition, (2) there must be a serious burden on the Examiner if restriction is not required. Applicants respectfully submit that the Examiner has not established that examining the groups together would impart a serious burden.

In particular, because the subject matter of all Groups are closely interrelated, there would be no burden on the Examiner if they were examined together. For example, Group I is related to both Groups VIII and IX, as disclosed for example, on page 6, lines 21-23 where it is stated that “[t]he modified plant ZFP can be a fusion polypeptide.” Likewise, Group IV (proteins comprising canonical zinc fingers) and Group V (proteins comprising non-canonical zinc fingers) are linked, for example, by the disclosure at page 7, lines 22-27, where it is stated, in part: “. . . in certain embodiments, a three-finger zinc finger protein is provided wherein the

first two fingers are of the C₂H₂ class but the third finger is non-C₂H₂ . . .” Groups II and III are also related, as evidenced, for example by the statement on page 8, lines 6-13, indicating, in part: “It will be readily apparent that various combinations of zinc fingers can be used in a single modified plant ZFP. For example, . . . the component fingers of a modified plant ZFP can be any combination of naturally-occurring plant zinc fingers, designed fingers and selected fingers.” Moreover, the two previous quotations from the specification, if taken together, indicate that the three zinc fingers of a protein comprising two canonical zinc fingers and one non-canonical zinc finger, can be any combination of naturally-occurring, designed, and selected fingers, thereby linking Groups II through V. Furthermore, at page 17, lines 2-4, the specification teaches that, in a zinc finger protein, each component zinc finger bind to a triplet (3-nucleotide) sequence. This being the case, a protein comprising a tandem array of zinc fingers (*i.e.*, more than one zinc finger) will bind to a target sequence having three or more nucleotides. Accordingly, the claimed subject matter of Group I is closely interrelated with the subject matter of each of Groups II through VII.

In further support of the rejection, the Examiner states “the modified plant zinc finger protein of Group I binds to a target DNA sequence of 3 or more contiguous nucleotides, which is not required of the polypeptides of Groups II-IX.” (Restriction Requirement, page 4). However, Applicants note that claim 1 is drawn to any modified plant zinc finger protein that binds a target sequence. Accordingly, since all the original claims classified in Groups I-IX depended directly or ultimately from claim 1, they all necessarily include the limitations of claim 1, including the limitation that the modified plant zinc finger protein bind to a target sequence. Similarly, the claims of Groups VIII and IX (fusions of modified plant zinc finger proteins and at least one functional domain) included all the limitations of original claim 14. Since the claims of these various Groups define the same essential characteristics of a single disclosed embodiment, varying in scope or breadth of definition of the same disclosed subject matter, a restriction requirement as between Groups I-VII and Groups VIII-IX is improper. (see, MPEP 806.03). In view of the close interrelatedness of the Groups, it would not be a serious burden on the Examiner to search and examine the inventions of Groups I through VII together as well as Groups VIII through IX together.

Because the claims are also related in modes of operation, functions and effects, there is no burden (let alone a serious burden) on the Examiner in searching and examining them together. Although the Office has asserted, without support, that Groups I through X are “unrelated,” Applicants note that the polypeptides of Groups I through IX have the same mode of operation (binding to DNA), the same functions (modulation of gene expression) and the same effects (changes in levels of gene expression). Again, examining the groups together would save

the Office time and effort, as a search for one group would necessarily reveal art relevant to the other groups.

The Restriction Requirement also asserts that "[t]he polypeptides of inventions I-IX are structurally and functionally different from the polynucleotide of invention X, and they can be used in different methods, *such as immunoassay methods for the polypeptides and hybridization methods for the polynucleotides.*" (emphasis added). Applicants respectfully remind the Office that the claimed polypeptides are non-naturally-occurring, "modified" proteins. See, for example, the specification at page 10, lines 17-24. Thus, it is difficult to understand how a non-naturally occurring polypeptide, as claimed, could be used in an immunoassay. What would be the target of such a hypothetical immunoassay? Similarly, it is difficult to imagine what could be detected in a hybridization assay that uses a polynucleotide encoding a non-naturally occurring protein as a probe. Accordingly, Applicants believe that the utilities asserted by the Office for Groups I through X are not specific, substantial or credible, but are merely "throwaway" utilities used to support an attempt to improperly restrict the claimed subject matter. Applicants respectfully remind the Office of the criteria for utility (66 Fed. Reg. 1092, 1098) and expect that the same criteria would apply to hypothetical utilities used by the Office to support the contention that examining the groups together would impart a serious burden on the Examiner.

In fact, both the claimed polypeptides of Groups I through IX, and the polynucleotides of Group X, are used in the same method, namely modulation of gene expression in plant cells, as taught throughout the specification and recited in claim 20. Thus, if the restriction between Groups I through IX and Group X is maintained, Applicants request that the Office explicitly identify specific and substantial utilities, that would be credible to one of skill in the art, for these alleged different "inventions," and provide evidence that one of skill in the art would have recognized that the use of a non-naturally occurring polypeptide in an immunoassay, and the use of a polynucleotide encoding a non-naturally-occurring polypeptide in a hybridization assay, was established as of the filing date of the present application. Applicants also request that the Office specifically identify the targets of such hypothetical immunoassays and hybridization assays.

In support of restriction between Group XI and Groups II-VII, the Office states that: "the polypeptides of Groups II-VII can be used in a materially different process of using those products, such as in immunoassay or immunization methods." (Restriction Requirement, page 5). With respect to the alleged use in immunoassays, Applicants submit that this is merely a "throwaway" utility for the claimed non-naturally-occurring polypeptides, as set forth above. With respect to the alleged use of the claimed polypeptides for immunization, Applicants note that immunization is a procedure used to protect a subject from infection by a pathogen. The

Office has presented no evidence of what pathogen the claimed polypeptides would be used to immunize against; therefore this is simply another "throwaway" utility, which is not specific, substantial or credible. Applicants therefore request that the Office identify the specific pathogen(s) that the polypeptides of Groups II-VII could be used to immunize against, or withdraw the restriction between Group XI and Groups II-VII.

In sum, the Examiner has not shown that it would impart a serious burden to examine all the claims together. At a minimum, Groups I through VII should be examined together and Groups VIII and IX should be examined together. Examination of these claims in one application would not place an undue burden on the Examiner, but would, in fact, actually save the Examiner time. In light of the Office's concerns about increasing numbers of applications, examination of the pending claims in a single application (rather than in eleven separate applications) would also save Patent Office resources.

Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application.

III. CONCLUSION

Applicants submit that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, they are invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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